WRITTEN OPINION International application No. PCT/IT 02/00681

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-5 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	
Inventive step (IS)	Claims	1-5
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Reference is made to the following documents:

D1: US-A-5584285
D2: DE-C-759110
D3: EP-A-0626180

Point V

1.1 D1 shows an apparatus for nebulising a liquid, e.g. for aerosol therapy (fig.4) having standard flap valves (140, fig.4). The subject-matter of claim 1 differs from the device of D1 in that a valve having a shutter movable between an open and a blocking position, said shutter being connected to a ring by deformable connecting elements between the ring and the shutter in order to anchor it to a tubular portion of the nebuliser. According to claim 1 the valve can be either an exhalation or inhalation valve.

1.2 Said construction is supposed to provide a valve with good sealing properties at rest and which oppose minimum resistance to opening/closing (see description page 4 1st paragraph). The problem to be solved by the invention can therefore be regarded as how to improve the valves of the apparatus of D1 to improve sealing and minimize closing/opening pressures of the valve.

1.3 The valve according to the characterising portion of claim 1 is described in document D2, also a check valve for a respiratory appliance (see col.2 lines 1-2 "Atemventil"), (see figures, deformable connecting elements 3, ring 2 tubular portion 1 and shutter 5) as providing the same advantages as in the present application (see col.2 lines 54-63 and lines 69-81). The skilled person would therefore regard it as a normal option to include the valve of D2 in the apparatus described in document D1 in order to solve the problem posed.

2. The subject-matter of claim 3 relates to a protective element for preventing introduction of foreign bodies into the nebuliser ampoule. The provision of such a feature to the device appears to be within the skills of skilled person. D1 shows a similar valve arrangement for the exhalation valve (124, fig.4) with hinged flap (see fig.5) and what can be called a secondary channel 148, fig.4. Therefore, the subject-matter of claims 3-5 does not appear to involve an inventive step either over a combination of D1 with D2 (D3 may also have been taken as the closest prior art).

3. The subject-matter of claim 2 is not shown by the available documents, nevertheless the choice of spiral connecting elements instead of straight ones as taught in D2, appears to be within the skills of a skilled person who has the possibility to experiment in order to make a valve with a determined opening pressure. No special technical effect has been with respect to the spiral form of the connecting elements, therefore it appears to be a matter of design.